

Appl. No. 10/019,676
Amdt. Dated December 9, 2004
Reply to Office Action of September 9, 2004

REMARKS

Claims 73-91 and 94-102 are pending in the present application. Claims 92-93 were withdrawn from consideration.

Applicants acknowledge and appreciate the Examiner's withdrawal of the rejections of claims 43-61, 63-65, and 67-72 under 35 U.S.C. 112, second paragraph.

The Examiner maintained the rejection of (the now cancelled) claims 43-61, 63-65 and 67-72 (which are claimed in the new claims 73-91 and 94-102) under 35 U.S.C. §112, first paragraph, for lacking enablement. According to the Examiner, there is insufficient enablement for the claimed methods in which the Pz crystals are not metal modified. This rejection is traversed in view of the amendment above to claim 82. Claim 82, as amended, clarifies that in all three immobilization methods the Pz crystal contains a metal electrode. Applicants thus ask that the rejection be withdrawn.

The Examiner also rejected the claims under 35 U.S.C. §103(a), based on the reasons set forth on pages 3-7 of the Office Action. The primary reference cited in each of these rejections is Bastiaans, et al. (U.S. Patent No. 4,735,906). The Examiner also has cited Larue (U.S. Patent No. 5,705,399), Thorns (U.S. Patent No. 5,510,241), Rajashekara, et al. (WO 98/03656), Willner, et al. (WO 98/40739), Willner, et al. (WO 97/04314), Masten, et al. (J. Bacteriol 175: 5359-65), and CAA78777.

The Examiner set forth as the basis for the rejections the following:

Appl. No. 10/019,676
Amdt. Dated December 9, 2004
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The Applicant traverses the rejection on the grounds that the prior art references cited by the Examiner do not render obvious the use of Pz crystals which were previously used in a test which was negative for the infectious agent. In particular, the Applicant argues "Although the Bastiaans and Larue references refer to washing and regenerating crystals for further use after obtaining a positive result, there is no disclosure of reusing crystals already tested against negative samples, and thus no recognition of the advantages for veterinary applications of methods having this feature." This argument is not found persuasive.

As was indicated in the prior action, each of the Bastiaans and Larue references teaches that, after use, the devices may be cleared of bound antibody/antigen using compounds with high ionic strength (including sodium chloride solutions), or low ph. Bastiaans, col. 6 lines 17-30; Larue, col. 16 lines 43-48. The Bastiaans reference further teaches that such clearance provides the disclosed device with the benefits of reusability. *Id.* See also, Larue, col. 16, *supra* (also teaching the benefit of reusability). Because the reference indicates that the device is reusable with such clearing, it would be apparent to those in the art that the device could be reused after a test, whether the result was positive or negative. While the reference used the example where the "substance that was detected" can be removed by the cleaning, from the indications of reusability in general, it would have been obvious to those in the art to clear the device as suggested whether the test was positive or not. The reference does not teach that the reusability is dependant upon a positive result in the prior tests. In view of these teachings, the Applicant's arguments in traversal are not found persuasive.

It is noted that the Applicant asserts the benefits of speed, simplicity, and reusability. However, these benefits are also recognized in the teachings of the references. See e.g., Bastiaans, col. 6, *supra* (referring to the simpler and fast operation of the disclosed device, and the benefits of reusability). Thus, these additional advantages do not appear to distinguish the claimed invention from the teachings of the references. Nor has the Applicant pointed out any feature of the claimed invention that provides unexpected advantages over the devices suggested by the prior art. The Applicant's arguments regarding the additional advantages are therefore not found persuasive.

In the penultimate sentence in the last paragraph above -- "Nor has the Applicant pointed out any feature of the claimed invention that provides unexpected advantages over the devices

Appl. No. 10/019,676
Amdt. Dated December 9, 2004
Reply to Office Action of September 9, 2004 ..

suggested by the prior art” -- suggests confusion as to what Applicants’ claimed invention is, versus what it is not, as compared to the cited art. Applicants’ claimed invention is not a “device,” and more specifically a device having unexpected advantages over devices of the cited art. Instead, the claimed invention is a method and a kit, specifically for performing an immunodiagnostic test for a veterinary disease in an animal (such as a chicken or a pig), comprising among its steps contacting a Pz crystal with a biological specimen from said animal to be tested, wherein said crystal was previously used in a test which was negative for an infectious agent associated with the veterinary disease. In short, the cited art does not teach or suggest the claimed invention.

In particular, the cited art does not teach or suggest methods of using Pz crystals for testing for a veterinary disease. More importantly, the cited art, alone or in combination, does not recognize the advantages, including convenience and cost effectiveness, of such methods having the claimed feature of reusing a Pz crystal that was previously used in a test which was negative for an infectious agent associated with the veterinary disease. The reusability of the Pz crystal that "was previously used in a test which was negative for said infectious agent" is why the claimed invention is advantageous for veterinary applications, as opposed to human applications. In particular, testing samples from different animals (such as chickens, which are typically tested in large numbers at one time) with the same Pz crystal, so long as previous test samples were negative for the infectious agent, is much more likely than when testing human samples, where there will be a heightened desire not to use a previously used crystal (e.g., to

Appl. No. 10/019,676
Amdt. Dated December 9, 2004
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avoid contamination) short of the crystal being first subjected to some sort of decontamination or sterilization treatment (i.e., analogous to the treatments used to regenerate positive Pz crystals).

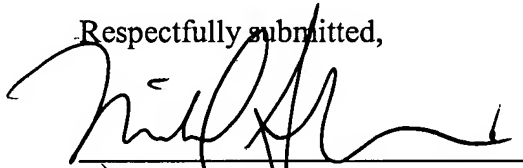
One thing is clear -- the cited art, alone or in combination, simply does not recognize or appreciate a link -- as the inventors have -- between reusability of the Pz sensor after coming into contact with a negative sample and the advantages of such a reusable sensor for veterinary applications.

For the foregoing reasons, Applicants ask that the obviousness rejections be withdrawn.

In view of the above amendments and remarks, reconsideration of the instant application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it will expedite allowance of the application.

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Respectfully submitted,



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